

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

H. LUNDBECK A/S, et al.,)	
)	
Plaintiffs,)	
)	
)	
v.)	C.A. No. 18-88-LPS
)	(Consolidated)
APOTEX INC., et al.,)	
)	
Defendants.)	
)	

**MOTION TO DISMISS DEFENDANT PRINSTON PHARMACEUTICAL INC. AND
ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD'S COUNTERCLAIMS
PERTAINING TO U.S. PATENT NOS. 9,125,908 AND 9,125,909**

Defendants Prinston Pharmaceutical Inc. and Zhejiang Huahai Pharmaceutical Co., Ltd. (collectively, “Prinston”) hereby move to dismiss without prejudice the Seventh, Eighth, Ninth, Tenth, Thirteenth, and Fourteenth Counterclaim Counts in Prinston’s Answer, Separate Defenses, and Counterclaims to the Second Amended Complaint (D.I. 310), which pertain to U.S. Patent Nos. 9,125,908 and 9,125,909 (the ’908 and ’909 patents). The ’908 and ’909 patents are not being asserted by Plaintiffs against Prinston or any other defendants in this consolidated case. Prinston is aware of no other defendants who have raised any counterclaims pertaining to the ’908 and ’909 patents. The granting of this motion will remove these two patents from the trial entirely. Dismissal of these counterclaims without prejudice will narrow the issues for trial and conserve both judicial resources and resources of the parties in preparing for trial, and will not have any prejudicial effect on Plaintiffs.

Defendants understand that Plaintiffs do not oppose a dismissal of these counterclaims, and acknowledge that the dismissal of these counterclaims would streamline the case, but Plaintiffs contend that dismissal of these counterclaims should be with prejudice. Yet, dismissal

with prejudice on a voluntary dismissal is a severe remedy and disfavored. Plaintiffs here cannot show any prejudice beyond the mere prospect of future litigation—the initiation of which would be within their own control. As such, a voluntary dismissal without prejudice is appropriate.

I. FACTUAL BACKGROUND

This is a pharmaceutical patent case brought under 35 U.S.C. § 271(e)(2). The '908 and '909 patents are among a dozen patents Plaintiffs listed in the FDA's "Orange Book" as covering their antidepressant drug Trintellix®. (D.I. 310, Prinston's Counterclaims ¶¶ 11-24). Prinston filed an abbreviated new drug application ("ANDA") at the FDA for a generic version of Trintellix®, and sent Paragraph IV ("PIV") notice letters to Plaintiffs challenging their Orange Book-listed patents, including the '908 and '909 patents. (*Id.*). Other pharmaceutical companies filed their own ANDAs for various generic versions of Trintellix®, and also challenged some of Plaintiffs' Trintellix®-related Orange Book patents. As a result, Plaintiffs filed multiple Hatch-Waxman cases which have now been consolidated under C.A. No. 18-88-LPS.

Two sets of facts are pertinent to the instant motion. First, although Plaintiffs filed multiple complaints and amended complaints against fourteen ANDA filers including Prinston and asserted many of their patents, they never asserted the '908 and '909 patents against any of the ANDA filers. This is true even after Prinston sent its PIV notice letter and asserted the counterclaims at issue relating to the '908 and '909 patents. Plaintiffs are currently seeking to amend their complaints to add an inducement of infringement count on a different patent, but the proposed amended complaints still do not contain any counts pertaining to the '908 and '909 patents. (D.I. 727). Second, apparently no other defendants asserted counterclaims relating to the '908 and '909 patents. Accordingly, Prinston's counterclaims subject to the instant motion are

the only asserted or proposed claims pertaining to the '908 and '909 patents in this consolidated case.

Plaintiffs sued Prinston on January 25, 2018, and amended their complaint on March 26, 2018. (D.I. 1 and D.I. 13 in C.A. No. 18-148-LPS, later consolidated). Plaintiffs filed a Second Amended Complaint against Prinston to add infringement claims, to which Prinston answered on June 14, 2019, and asserted declaratory-judgment counterclaims pertaining to the '908 and '909 patents now at issue in this motion. (D.I. 310, Prinston Counterclaims ¶ 76 *et seq.*).

Furthermore, as mentioned above, Plaintiffs have a currently-pending motion for a Third Amended Complaint in order to add additional infringement claims. (D.I. 727). None of the original, added, and now proposed additional infringement claims in these complaints and proposed amended complaint is directed to the '908 and '909 patents. To summarize, Plaintiffs filed and proposed several iterations of their complaint against Prinston, asserting several of their Orange Book patents, but made a strategic choice and never asserted the '908 and '909 patents.

The parties in the consolidated case engaged in expert discovery over the past two months. After the exchange of opening expert reports with Plaintiffs on April 16, 2020, Prinston understood that, apparently, no other parties asserted the '908 and '909 patents in a case, because Plaintiffs did not address these two patents in the expert reports they served. Counsel for Prinston met and conferred with Plaintiffs' counsel on April 28, 2020, to ask if Plaintiffs would stipulate to a dismissal of all '908 and '909 patent-related counterclaims without prejudice. Defendants understand that Plaintiffs would only stipulate to a dismissal *with prejudice*. (See D.I. 776). On May 29, 2020, Prinston and Plaintiffs filed a stipulation with the Court, in which Plaintiffs state that they do not oppose Defendants' request for leave to file a motion to dismiss, but will oppose the motion to dismiss without prejudice. (*Id.* at 2).

On June 5, 2020, all parties exchanged a second round of expert reports. Plaintiffs' experts again did not directly address the '908 and '909 patents, other than to state in one sentence that these patents are very similar to another patent in the case and can be subject to the same validity and infringement analyses. *See* Declaration of Brent Batzer, Ex. 1.

II. THE SPECIFIED COUNTERCLAIMS SHOULD BE DISMISSED WITHOUT PREJUDICE, BECAUSE PLAINTIFFS WOULD NOT SUFFER ANY PREJUDICE

Plaintiffs do not oppose the dismissal of Prinston's counterclaims pertaining to the '908 and '909 patents. Plaintiffs have not asserted these two patents against any ANDA filer, and the dismissal would remove these two patents from this consolidated case altogether and conserve judicial and party resources. However, Plaintiffs would not agree to trying the issues common to all ANDA filers first, and saving the fight over the '908 and '909 patents to a later date. Instead, Plaintiffs insist upon a dismissal *with prejudice*. Plaintiffs' position is not supported by law, because they cannot show any prejudice beyond the unlikely prospect of subsequent litigation if the counterclaims are dismissed without prejudice.

The default of a voluntary dismissal is without prejudice. FED. R. CIV. P. 41(a)(2) (“Unless the order states otherwise, a dismissal under this paragraph (2) is without prejudice.”). A dismissal without prejudice is discretionary, but generally should be granted “unless it would subject ‘the defendant to plain prejudice beyond the prospect of subsequent litigation.’” *In re Wellbutrin XL Antitrust Litig.*, 268 F.R.D. 539, 543 (E.D. Pa. 2010), quoting *Westinghouse Elec. Corp. v. United Elec. Radio & Mach. Workers of Am.*, 194 F.2d 770, 771 (3d Cir. 1952). When “[t]he dismissal . . . left the objecting defendants in position essentially no different from that they occupied before the suit was filed,” there is “no prejudice to their interests.” *Westinghouse*, 194 F.2d at 771 (dismissal without prejudice upheld).

Plaintiffs in this case will not be prejudiced “beyond the prospect of subsequent litigation.” *Id.* Plaintiffs have not expended any significant resources in this litigation specifically directed to the ’908 and ’909 patents, and what work they had done regarding these patents would be usable in future litigation in the unlikely event of such litigation. Two rounds of expert reports have now been exchanged, and only one of Plaintiffs’ experts mentioned that his analyses on a different patent could be copied and pasted to apply to the ’908 and ’909 patents. *See* Declaration of Brent Batzer, Ex. 1. Plaintiffs proffered no independent analyses directed to the ’908 and ’909 patents whatsoever. Quite simply, Plaintiffs will suffer no prejudice at all by the voluntary dismissal of the counterclaims as to the ’908 and ’909 patents.

The requested dismissal without prejudice would not confer any strategic advantage upon Prinston. It is actually quite unlikely that *any* future litigation regarding the ’908 and ’909 patents would arise between Prinston and Plaintiffs. The reality of a so-called “innovator” or brand pharmaceutical company facing multiple ANDA filers challenging its patents is that, once some of the ANDA filers win their patent challenges and are cleared for product launching, the market “genericizes” and there would be no incentive for the brand company to continue fighting other ANDA filers on all of its patents. Conversely, if the brand company could win the “first wave” cases against ANDA filers based on some, but not necessarily all, of its Orange Book-listed patents that it has chosen to assert in the cases, there is often no need to fight over other, not-asserted, patents later against the same defendants, because the marketing of the generic alternatives would already be blocked. 35 U.S.C. § 271(e)(4). In the context of this case involving fourteen ANDA filers and Plaintiffs’ choice not to assert the ’908 and ’909 patents, it

is unlikely that, win or lose, there would be a future litigation between Prinston and Plaintiffs involving these patents.¹

While Plaintiffs will suffer no cognizable prejudice by a voluntary dismissal without prejudice of certain counterclaims, Prinston would suffer significant prejudice by a dismissal *with* prejudice. A dismissal with prejudice could be construed as an entirely unearned decision on the merits, has “severe” consequences to the claimant, and must be “disfavored.” *See Papera v. Pennsylvania Quarried Bluestone Co.*, 948 F.3d 607, 611 (3d Cir. 2020).

For the foregoing reasons, Prinston respectfully requests that this Court grant its motion and dismiss without prejudice the Seventh Count, Eighth Count, Ninth Count, Tenth Count, Thirteenth Count, and Fourteenth Count in the Counterclaims of the Answer, Separate Defenses, and Counterclaims to the Second Amended Complaint (D.I. 310).

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¹ Per the FDA Orange Book, Plaintiffs have represented that the '908 and '909 patents expire on the same date as the '910 patent in this case (June 15, 2027). Other patents in the litigation are stated in the Orange Book as also expiring on the same date, or as late as 2031 and 2032. None of the patents-in-suit asserted against Prinston expire earlier than the '908 and '909 patents.